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10/573,222	03/23/2006	Daniel Raederstorff	22212USWO C038435/0196793	4962
Stephen M Haracz Bryan Cave 1290 Avenue of the Americas New York, NY 10104			EXAMINER	
			TATE, CHRISTOPHER ROBIN	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/573 222 RAEDERSTOREE ET AL Office Action Summary Examiner Art Unit Christopher R. Tate 1655 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 12 January 2009. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 14-17 and 19-34 is/are pending in the application. 4a) Of the above claim(s) 1-13.16.19 and 20 is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 14, 15, 17, and 21-34 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date. Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)

Paper No(s)/Mail Date 0508

5) Notice of Informal Patent Application

6) Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12 January 2009 has been entered.

Claims 14, 15, 17, and 21-34 are presented for examination on the merits (claims 1-13, 16, 19, and 20 remain withdrawn for the reasons of record).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 33 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New claim 33 recites the range limitations for the epigallocatechin gallate as being "in an amount "from 100 mg to 300 mg" and the PPARy ligand as being "in an amount of from 8 mg to 100 mg". However, the examiner could not find adequate support for these two range limitations

within the instant specification (as well as the original claims), including within the areas that

Applicants point to therein for such support.

Accordingly, these two range limitations are deemed new matter as the original disclosure does not appear to provide adequate support therefor.

Claims 24, 26, 28, 30, and 32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the intended use of treating and/or inhibiting body weight gain or adipose tissue weight gain associated with the use of a PPARy ligand does not reasonably provide enablement for the intended use of preventing such body weight gain or adipose tissue weight gain in vivo (including in a subject being administered a PPARy ligand such as the elected species - ligustilide, in combination with EGCG). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

- 1) the nature of the invention;
- 2) the breadth of the claims:
- 3) the predictability or unpredictability of the art
- 4) the amount of direction or guidance presented;
- 5) the presence or absence of working examples;
- the quantity of experimentation necessary;
- 7) the state of the prior art; and,
- 8) the relative skill of those skilled in the art;

With respect to the Wands factors above (particular as they pertain to the quantity of experimentation necessary as well as the state of the prior art within the medical field), Applicants have reasonably demonstrated/disclosed that the claimed pharmaceutical composition is useful as a therapeutic agent for treating and/or inhibiting body weight gain or adipose tissue weight gain associated with the use of a PPARγ ligand in vivo. However, the claims also encompass the claimed pharmaceutical composition having the intended use of preventing such body weight gain or adipose tissue weight gain which is clearly beyond the scope of the instantly disclosed/claimed invention. Please note that the term "prevent" is an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does --treat-- or --inhibit--, especially since it is notoriously well accepted in the medical art that the vast majority of afflictions/disorders suffered by mankind cannot be totally prevented with current therapies - including preventing such disorders as those associated with in vivo administration of PPARγ ligands (e.g., body weight gain and adipose tissue weight gain associated therewith).

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to make and/or use the instantly claimed pharmaceutical composition in a manner consistent with providing the intended in vivo functional effects instantly claimed with respect to "preventing" body weight gain or adipose tissue weight gain associated with the use of a PPARy ligand.

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It is suggested that the terms "preventing" (claim 24, line 3) and "prevents" (claim 26, line 6) be omitted from claims 24 and 26, and that these terms be replaced with the words --inhibiting-- and --inhibits--, respectively, to overcome the USC 112, first paragraph rejection immediately above in response to this Office action.

Claim Rejections - 35 USC § 102

Claims 14, 15, 17, 21, 22, and 24-32 are/stand rejected under 35 U.S.C. 102(b) as being anticipated by Cui (CN 1120953, Derwent Abstract provided), with evidence provided by Ahmad et al. (Nutrition Reviews, March 1999) and Ko (Jap. J. Pharmacol., 1980)* for the reasons of record which are restated and expanded upon below.

Cui teaches a therapeutic drink composition containing green tea (10-25%) and Ligusticum wallichii (5-12%) out of 5 total ingredients as a health-benefiting drink. Green tea is known to be an excellent source of catechins (as evidence - see, e.g., Ahmad et al., entire document including page 78, second column - last paragraph). Epigallocatechin gallate is the major catechin found in green tea, and one cup of green tea can contain up to 200 mg of epigallocatechin gallate (as evidence, see, e.g., Ahmad et al., page 79, first column, third paragraph). Thus, since 10-25% of the composition taught by Cui contains green tea, one cup of the reference composition would contain 20-50 mg of epigallocatechin gallate therein (please also note that portions larger than a cup of the reference drink would contain higher amounts of EPGC therein - on an ascending scale). Ligusticum wallichii is known to contain several phthalide compounds, one of which is ligustilide (as evidence - see, e.g., entire document including abstract of Ko). Thus, the composition taught by Cui would inherently contain

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ligustilide. Please note that based upon the amount of Ligusticum wallichii within the therapeutic drink composition taught by Cui, the level of ligustilide therein would inherently be within the broad range instantly claimed - i.e., within the range of 1-1000 mg (e.g., within a certain portion of the reference drink such as a cup or larger portion thereof, given that the amounts of ligustilide and ECGC instantly claimed are not defined in relative terms: i.e., with respect to being contained within a particular amount of the claimed composition).

Therefore the reference is deemed to anticipate the instant claims above.

* Again please note that the Ahmad et al. and Ko references are not being cited as prior art within the 35 U.S.C. 102(b) rejection above but instead are being cited as evidence to show inherent properties of green tea and Ligusticum wallichii within the Cui composition.

Claim Rejections - 35 USC § 103

Claims 14, 15, 17, 21, 22, and 24-34 are/stand rejected under 35 U.S.C. 103(a) as being unpatentable over Cui (CN 1120953, Derwent Abstract provided), with evidence provided by Ahmad et al. (Nutrition Reviews, March 1999) and Ko (Jap. J. Pharmacol., 1980)* for the reasons of record which are restated below.

Cui beneficially teaches a therapeutic drink composition containing green tea (10-25%) and Ligusticum wallichii (5-12%) out of 5 total ingredients as a health-benefiting drink. Green tea is known to be an excellent source of catechins (as evidence - see, e.g., Ahmad et al., entire document including page 78, second column - last paragraph). Epigallocatechin gallate is the

major catechin found in green tea, and one cup of green tea can contain up to 200 mg of epigallocatechin gallate (as evidence, see, e.g., Ahmad et al., page 79, first column, third paragraph). Thus, since 10-25% of the composition taught by Cui contains green tea, one cup of the reference composition would contain 20-50 mg of epigallocatechin gallate therein (please also note that portions larger than a cup of the reference drink would contain higher amounts of EPGC therein - on an ascending scale). Ligusticum wallichii is known to contain several phthalide compounds, one of which is ligustilide (as evidence - see, e.g., entire document including abstract of Ko). Thus, the composition taught by Cui would inherently contain ligustilide. Please note that based upon the amount of Ligusticum wallichii within the therapeutic drink composition taught by Cui, the level of ligustilide therein would intrinsically be within the broad range instantly claimed - i.e., within the range of 1-1000 mg (e.g., within a certain portion of the reference drink such as a cup or larger portion thereof, given that the amounts of ligustilide and ECGC instantly claimed are not defined in relative terms: i.e., with respect to being contained within a particular amount of the claimed composition).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a therapeutic health-benefiting beverage comprising the instantly claimed components of catechins found in green tea, such as epigallocatechin gallate, and ligustilide, found in *Ligusficum wallichii* based on the beneficial teachings of Cui. The adjustment of particular conventional working conditions (e.g., determining therapeutically suitable amounts of green tea and *Ligusficum wallichfi* therein, and thus the amounts of epigallocatechin gallate and ligustilide respectively that would be health-benefiting) is deemed

merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

* Again please note that the Ahmad et al. and Ko references are not being cited as prior art within the USC 102(b) and 103 rejections above but instead are being cited as evidence to show inherent properties of green tea and *Ligusticum wallichii* within the Cui composition.

Applicants' arguments concerning the USC 102(b) and USC 103 rejections above over the Cui reference have been carefully considered but are not deemed to be persuasive of error in the rejections. Applicants argue that the Examiner has erred in having asserted that the health-benefiting drink (having various therapeutic function effects disclosed therein) taught by Cui clearly reads upon a pharmaceutical composition including because Cui provides no scientific evidence or reasoning pertaining to use of the disclosed drink for treatment of disease, and because additional herbal or botanical ingredients are disclosed by Cui as included in the beverage. Thus, one skilled in the art would understand Cui as disclosing a mixture of ingredients with a promotional statement of the composition's possible health benefits.

However, please note that the therapeutic health-benefiting drink expressly taught by Cui clearly reads upon the instantly claimed pharmaceutical composition - i.e., the therapeutic drink

disclosed by Cui is in a well-accepted pharmaceutical form adapted for oral consumption thereof. Accordingly, it is not discernable to the Examiner as to how such a well-accepted pharmaceutical form "strains credulity" as argued by Applicants within their 12 January 2009. Further, as previously discussed, the instantly claimed composition is one which comprises the instantly claimed ingredients. Accordingly, this open language (i.e., "comprising") permits the inclusion other ingredients therein. Applicants also argue that the Cui reference lacks an "identity of invention" with the claimed composition which comprises a catechin found in green tea and a PPARy ligand - such as the elected species; ligustilide. However, for the reasons fully set forth in the previous Office action, the health-benefiting drink composition taught by Cui inherently comprises a catechin such as epigallocatechin gallate (inherently contained within green tea) and ligustilide (inherently contained within Ligusticum wallichii) - including being present within such a composition so as to provide the broad dosage ranges of each therein - as best understood by the claim language, as drafted (e.g.,, the instant claim language still does not define in a positive manner as to what such a dosage of EGCG and/or ligustilide is in relation to). Applicants further argue the Cui reference is not an enabling document because relative amounts of a catechin found in green tea and a PPARy ligand that would be effective in treating or preventing any disease such as hypoglycemia are notably lacking in Cui. However, for the reasons fully discussed above, the Cui reference is deemed enabling with respect to disclosing therapeutic orally-consumable composition which inherently comprises the instantly claimed ingredients (including within the broad instantly claimed amount ranges of the cited claims).

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With respect to the USC 102 rejection over the Cui reference, Applicants also argue that this rejection is legally deficient since each and every element of the claimed invention must be demonstrated in a single prior art reference. Thus, attempting to rely on Ahmad and Ko to fill in the factual gaps in Cui is improper. However, as fully discussed within the USC 102 and 103 rejection over Cui, the Ahmad et al. and Ko references are not being cited as prior art therein but instead are being cited as evidence to show inherent properties of green tea (i.e., that the green tea within the therapeutic drink composition taught by Cui inherently contains EGCG) and Ligusticum wallichii (i.e., that the Ligusticum wallichii within the therapeutic drink composition taught by Cui inherently contains ligustilide).

Applicant further argues that combinations of EGCG and rosiglitazone provide surprising unexpected results. However, please note that the claims have been examined insofar as they read upon the elected species - i.e., EGCG and ligustilide (not rosiglitazone). Further, in terms of the broader aspect of any unexpected results achieved by the combination of EGCG and a PPARy ligand such as ligustilide, please again note that, as drafted, the amounts of ligustilide and ECGC instantly claimed are not defined in relative terms: i.e., with respect to being contained within a particular amount of the claimed pharmaceutical composition.

Claims 14, 15, 17, and 21-34 are/stand rejected under 35 U.S.C. 103(a) as being unpatentable over Morre et al. (US 6,410,061) and Zhao (US 2003/0165580) for the reasons set forth in the previous Office action which are restated and expanded upon below.

A pharmaceutical composition, including in the form of a solid unit dosage, comprising a green tea catechin such as epigallocatechin gallate and ligustilide is claimed.

Morre et al. beneficially teach a pharmaceutical composition (including, e.g., in a solid unit dosage form such as a tablet or capsule) useful for treating various cancers including ovarian cancer, which comprises one or more green tea catechins such as epigallocatechin gallate as the active ingredient(s) therein. Morre et al. also teach that an effective daily dosage of epigallocatechin gallate is about 0.15 mg to about 1500 mg per kg body weight (within the instantly claimed dosage amount - as best understood). See entire document including Abstract; col 6, line 29 - col 17, line 35; and claims. Morre et al. do not teach the inclusion of ligustilide therein.

Zhao beneficially teaches a pharmaceutical composition (including, e.g., in a solid unit dosage form such as a tablet or capsule) useful for treating/controlling gynecological diseases including cancers such as ovarian cancer, which comprises ligustilide as the active ingredient therein. Zhao also teaches that an effective daily dosage of ligustilide is 1-10 mg per kg body weight which - as disclosed by Zhao, corresponds to 50-500 mg/adult/dose for a 50 kg adult (within the instantly claimed dosage amount - as best understood). See entire document including Abstract, paragraphs [0017]-[0019], [0036]-[0037], [0090]-[0093], Examples, and claims.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for the same purpose (i.e., for treating cancer including ovarian cancer) and for the following reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. The idea for combining

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them flows logically from their having been used individually in the prior art. In re Kerkhoven, 626 F.2d 846, 850, 205 U.S.P.Q. 1069 (CCPA 1980); In re Sussman, 1943 C.D. 518.; In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). The result-effective adjustment of particular conventional working conditions (e.g., determining appropriate anti-cancer amounts thereofincluding within the instantly claimed ranges) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicants' arguments concerning the USC 103 rejection above over Morre et al. and Zhao have been carefully considered but are not deemed to be persuasive of error in the rejection. Applicants argue that the rejection is improper because it is devoid of analysis in support of the modification in that there are conclusionary statements indicating it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for the same purpose, but that the Examiner failed to explain why one would provide such a modification. Thus, Applicants argue that the rejection is legally deficient. However, as further

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discussed above, the USC 103 rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. The idea for combining them flows logically from their having been used individually in the prior art. In re Kerkhoven, 626 F.2d 846, 850, 205 U.S.P.Q. 1069 (CCPA 1980); In re Sussman, 1943 C.D. 518.; In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Applicants further argue that one skilled in the art would not have expected to achieve a pharmaceutical composition for the intended purpose of effecting glucose tolerance as claimed wherein the effective amount of each ingredient reduces fasted glucose concentration and prevents weight gain or adipose tissue gain associated with use of a PPARy ligand. However, these instantly claimed functional effects would be intrinsic to a composition comprising anticancer effective amounts of EGCG and ligustilide therein, as reasonably suggested by the combined teachings of the cited references - e.g., based upon the beneficial teachings provided by Morre et al. and Zhao including with respect to the useful anti-cancer amounts of such ingredients (each of which are within the instantly claimed amount ranges - as best understood) as disclosed therein.

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Double Patenting

Claims 14, 15, 17 and 21-34 are/stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-24 of copending Application No. 10/556,199, in view of Hara et al. (US 5,318,986).

The instantly claimed invention is drawn to a pharmaceutical composition comprising a green tea catechin (such as epigallocatechin) and ligustilide therein, whereas the invention defined by the cited claims of Appl. No. '199 is drawn to a pharmaceutical composition (for the intended purpose of treating/preventing diabetes) comprising ligustilide, therein. Hara et al. teaches the use of a composition comprising epigallocatechin gallate (from green tea) for effectively treating diabetes (see entire document). Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the claimed anti-diabetic ligustilide pharmaceutical composition set forth in Appl. No. '199 with epigallocatechin gallate based upon the beneficial teachings provided by Hara et al. with respect to epigallocatechin gallate also being an effective anti-diabetic agent.

This is a provisional obviousness-type double patenting rejection.

With respect to the obviousness-type double patenting rejection above, Applicants argue that the Examiner only asserted in the previous Office action that making the combination of ligustilide with EGCG would have been obvious over the '199 application in view of Hara et al., and that the instantly claimed composition has been amended so as to now recite "wherein the composition is a pharmaceutical composition". However, the provisional obviousness-type double patenting rejection above is deemed proper for the reasons set forth therein - i.e., the

instantly claimed invention is drawn to a pharmaceutical composition comprising a green tea catechin (such as epigallocatechin) and ligustilide therein, whereas the invention defined by the cited claims of Appl. No. '199 is drawn to a pharmaceutical composition (for the intended purpose of treating/preventing diabetes) comprising ligustilide therein. Hara et al. teaches the use of a composition comprising epigallocatechin gallate (from green tea) for effectively treating diabetes (see entire document). Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the claimed anti-diabetic ligustilide pharmaceutical composition set forth in Appl. No. '199 with epigallocatechin gallate based upon the beneficial teachings provided by Hara et al. with respect to epigallocatechin gallate also being an effective anti-diabetic agent.

With respect to the obviousness-type double patenting rejection above, Applicants further argue that one skilled in the art would not have expected to achieve a pharmaceutical composition for the intended purpose of effecting glucose tolerance as claimed wherein the effective amount of each ingredient reduces fasted glucose concentration and prevents weight gain or adipose tissue gain associated with use of a PPAR γ ligand. However, these instantly claimed functional effects would be intrinsic to a composition intended to effectively treat diabetes comprising EGCG and ligustilide therein.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur. 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher R. Tate/ Primary Examiner, Art Unit 1655